

**Application No.:** 10/566,829  
**Filing Date:** January 31, 2006

### **REMARKS**

Claims 1 and 2 have been amended. Claim 9 is added. Claim 3 is cancelled with this amendment. Claims 1 and 2 remain under consideration and have been amended to address the remaining grounds of rejection as discussed further below. New claim 9 is added which finds support in Tables 1-7 on pages 20-26 of the present specification. No new matter is added.

The withdrawal of the rejections of the claims as anticipated by Johnson and as obvious over Johnson in combination with Hai and Fukuchi, Ninomiya, and Zabik and Aldrich is gratefully acknowledged. Applicants gratefully acknowledge withdrawal of the obviousness-double patenting rejection in light of the previous amendments.

#### **Telephonic interview**

The undersigned thanks Examiners Ricci and Marschel for the helpful telephonic interview summarized on page 3 herein.

#### **Rejection under 35 U.S.C. § 112, second paragraph**

Claims 1-3 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action states that the recitation of “or” in “kappa ( $\kappa$ )-carrageenan and/or iota ( $\iota$ )-carrageenan” makes it unclear.

Applicants have amended claim 1 to recite “wherein the composition comprises granisetron hydrochloride, a carrageenan...” to clarify that the composition comprises both granisetron hydrochloride (a 5-HT<sub>3</sub> receptor) and a carrageenan. The further limitation “wherein the carrageenan is kappa ( $\kappa$ )-carrageenan and/or iota ( $\iota$ )-carrageenan” is moved to the second to the last line of the claim. Accordingly, claim 1 is clearly directed to the Examiner’s second interpretation on page 4 of the Office Action that a 5-HT<sub>3</sub> receptor must be present with either kappa ( $\kappa$ )-carrageenan and/or iota ( $\iota$ )-carrageenan.

In view of Applicants’ amendments and comments above, withdrawal of the rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

Claims 1 and 3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson (US 6,316,027) in view of Ninomiya, et al. (US 5,932,235).

Claim 1 has been amended to include limitations finding basis in cancelled claim 3, that the 5-HT<sub>3</sub> receptor is granisetron hydrochloride.

Claim 1 has been amended to a particularly preferred embodiment which includes D-sorbitol and glycerin. Support is found in Example 1 (pages 18-19) and Example 30 (see Table 7, page 26 of the present specification). Claim 9 is added which limits the concentration of glycerin to a preferred range as taught in the present specification in Tables 1-7 on pages 20-26.

Granisetron hydrochloride has a tendency to foam when blended with carrageenan, locust bean gum and sodium polyacrylate. While the composition may be defoamed with an antifoam agent such as silicone resin emulsion, when silicone resin emulsion is used to defoam the composition, the jellied composition takes on an unattractive white color due to the antifoam agent. Upon inclusion of D-sorbitol and glycerin in a composition comprising granisetron hydrochloride, the specified carrageenans, locust bean gum and sodium polyacrylate, the foaming problem is resolved without adversely affecting the appearance of the final product.

Johnson, et al. is directed to a final composition that is freeze-dried. Accordingly, Johnson, et al. do not teach anything regarding a foaming problem for granisetron hydrochloride and there is no teaching in Johnson, et al. on addition of glycerin and D-sorbitol to granisetron hydrochloride.

Regarding Ninomiya, et al., Ninomiya, et al. do not teach compositions containing either granisetron hydrochloride or glycerin. Accordingly, Ninomiya, et al. do not teach or suggest anything regarding the foaming problem discussed above.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

Claims 1 and 3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson (US 6,316,027) in view of Ninomiya, et al. (US 5,932,235).

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The Examiner has rejected claim 2 as being unpatentable over Johnson (US 6,316,027) in view of Ninomiya, et al. (US 5,932,235) as applied to claim 1 above, in further view of Hai (US 6,767,558). The Examiner asserts that it would have been obvious to one of ordinary skill in the art to combine a reductant as taught by Hai, et al. with the composition as taught by Johnson. However, since claim 2 depends from claim 1, which is neither taught nor suggested by Johnson in view of Ninomiya, et al. as discussed above, the invention defined in claim 2 is also patentably distinguished from the references, alone or in combination. Applicants respectfully request the withdrawal of the rejection.

#### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

#### **CONCLUSION**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.


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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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